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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,231	10/03/2003	Eric Charles Holland	D6534	3560

7590 09/23/2004

Dr. Benjamin Adler  
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Houston, TX 77071

EXAMINER

ALONZO, NORMA LYN

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/679,231	<b>Applicant(s)</b> HOLLAND, ERIC CHARLES	
	<b>Examiner</b> Norma C Alonzo	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

1. Claims 1-20 are pending in the instant application.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4 and 18-20, drawn to a non-human transgenic animal expressing a reporter gene coding for a protein capable of producing light upon metabolizing a substrate wherein said reporter gene is operably linked to a promoter which is activated by cell cycling, classified in class 800, subclass 13.
- II. Claims 5-9, drawn to a method for assessing the tumorigenic potential of oncogenes or mutated tumor suppressor genes comprising cross-breeding a non-human transgenic animal expressing a reporter gene coding for a protein capable of producing light upon metabolizing a substrate, classified in class 800, subclass 3.
- III. Claims 10-13, drawn to a method for assessing the tumorigenic potential of a candidate carcinogen comprising treating a transgenic non-human animal expressing a reporter gene coding for a protein capable of producing light upon metabolizing a substrate with said candidate carcinogen, classified in class 800, subclass 3.

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- IV. Claims 14-17, drawn to a method for assessing the anti-tumor effects of an anti-carcinogen or therapeutic modality comprising inducing tumor formation in a transgenic non-human animal, inducing tumor formation in said animal, treating said animal with said anti-carcinogen or treatment modality, classified in class 800, subclass 3.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Group I is directed to a transgenic non-human animal whereas Group II is directed to a method for assessing tumorigenic potential of oncogenes or mutated tumor suppressor genes, Group III is directed to a method for assessing the tumorigenic potential of a candidate carcinogen and Group IV is directed to a method for assessing the anti-tumor effects of an anti-carcinogen or therapeutic modality.

Whereas the inventions of Group I and Group II are related because the transgenic non-human animal of Group I could be used in the method of Groups II, it is patentably distinct because the transgenic non-human animal of Group I could be used in a materially different process of using said animal other than the method of Group II

such as the method of Groups III or IV or isolating cells from said transgenic animal to establish a cell line having cells expressing a reporter gene coding for a protein capable of producing light upon metabolizing a substrate.

Whereas the inventions of Group I and Group III are related because the transgenic non-human animal of Group I could be used in the method of Groups III, the inventions are patentably distinct because the transgenic non-human animal of Group I could be used in a materially different process of using said animal other than the method of Group II such as the method of Groups II or IV or isolating cells from said transgenic animal to establish a cell line having cells expressing a reporter gene coding for a protein capable of producing light upon metabolizing a substrate.

Whereas the inventions of Group I and Group IV are related because the transgenic non-human animal of Group I could be used in the method of Groups IV, the inventions are patentably distinct because the transgenic non-human animal of Group I could be used in a materially different process of using said animal other than the method of Group IV such as the method of Groups II or III or isolating cells from said transgenic animal to establish a cell line having cells expressing a reporter gene coding for a protein capable of producing light upon metabolizing a substrate.

Therefore, because the inventions are different, each from the other, they are patentably distinct and will require a separate search in the patent and non-patent literature.

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3. The inventions of Groups II-IV are patentably distinct. The groups are directed to methods wherein method steps comprise compositions that have different modes of operation, function and physical characteristics. For example, Group II comprises a method step wherein a transgenic non-human animal is cross-bred with other animals whereas Group III comprises a method step wherein a transgenic non-human animal is treated with a candidate carcinogen to determine said carcinogen's tumorigenic potential whereas Group IV comprises a method step wherein tumor formation is induced in a transgenic non-human animal and said animal is treated with an anti-carcinogen or therapeutic modality. Therefore, because the inventions are different, each from the other, they are patentably distinct and will require a separate search in the patent and non-patent literature.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

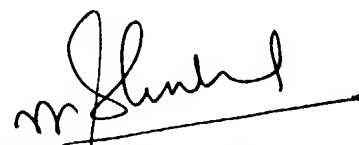
remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Norma C Alonzo whose telephone number is 571-272-2910. The examiner can normally be reached on 8-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NCA



RAM R. SHUKLA, PH.D.  
PRIMARY EXAMINER